REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on May 19, 2010. A Petition for a three month extension of time is submitted herewith this Amendment. The Director is authorized to charge $1,110.00 for the Petition for a three month extension of time and any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712036-00697 on the account statement.

Claims 1 and 3-13 are pending in the application. Claim 2 was previously canceled without prejudice or disclaimer. In the Office Action, Claims 1 and 3-12 are rejected under 35 U.S.C. §112. Claim 13 is rejected under 35 U.S.C. §103. In response, Applicants have amended Claims 1, 5 and 7-12 and have canceled Claims 3 and 6 without prejudice or disclaimer. The amendments do not add new matter and are supported in the specification at, for example, originally filed Claims 3 and 6; and the specification (WO 2005/002612) at, for example, page 6, lines 13-18. For at least the reasons set forth below, Applicants respectfully submit that the rejections be reconsidered and withdrawn.

In the Office Action, Claims 1 and 3-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Patent Office asserts that Claims 1 and 3-12 are indefinite because i) "it is unclear what amount of the claimed product is administered and therefore it is unclear what elements are necessary to practice the claimed invention"; and ii) "[t]he terms 'protein source', 'lipid source' and 'carbohydrate source' render the claims indefinite because it is unclear what is the scope of these terms." See, Office Action, page 4, lines 1-17. Applicants respectfully disagree for at least the reasons set forth below.

Currently amended independent Claim 1 recites, in part, methods for treating and/or improving insulin resistance by reducing insulin resistance, the method comprising administering to a patient having reduced insulin sensitivity a nutritional and/or pharmaceutical product comprising lactulose in an amount from about 0.2 to about 90% by total weight of the product. Currently amended independent Claim 5 recites, in part, methods for treating and/or improving insulin resistance comprising administering to a patient a composition comprising lactulose, wherein the lactulose is administered in an amount of from 0.1 to 1.5g per kg body weight. The

amendments do not add new matter and are supported in the specification at, for example, originally filed Claims 3 and 6; and the specification (WO 2005/002612) at, for example, page 6, lines 13-18.

The standard for determining whether the definitiveness requirement is met under 35 U.S.C. § 112, ¶ 2 is "whether those skilled in the art would understand what is claimed when the claim is read in light of the Specification." *Orthokinetics Inc. v. Safety Travel Chairs Inc,* 1 U.S.P.Q. 2d 1081-1088 (Fed. Cir. 1986). "If the claims, read in light of the Specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the Courts can demand no more." *North American Vaccine Inc. v American Cyanamid Co.,* 28 U.S.P.Q. 2d 1333, 1339 (Fed. Cir. 1993). By statute, 35 U.S.C. 112, Congress has placed no limitations on how an applicant claims his invention, so long as the specification concludes with claims which particularly point out and distinctly claim that invention." *In re Pilkington,* 162 U.S.P.Q. 145, 148 (C.C.P.A. 1996).

With respect to the Patent Office's assertion that "it is unclear what amount of the claimed product is administered and therefore it is unclear what elements are necessary to practice the claimed invention," Applicants respectfully disagree and submit that such a narrowing of the claim is not necessary, nor is it required in order for the present claims to be sufficiently definite. Further, since the present claims have been amended to recite specific amounts of lactulose, the claims now recite specific amounts of each of the ingredients currently claimed and, as such, satisfy the definiteness requirements under 35 U.S.C. §112, second paragraph. In this regard, Applicants submit that it is not necessary to claim the "amount of the claimed product [that] is administered," as suggested by the Patent Office, because the claims set forth either a specific weight percentage of lactulose required, or a specific amount of lactulose required to be administered to a patient.

Regarding the Patent Office's assertion that "[t]he terms 'protein source', 'lipid source' and 'carbohydrate source' render the claims indefinite because it is unclear what is the scope of these terms," Applicants respectfully disagree and submit that the skilled artisan would immediately appreciate the meaning of the phrases "protein source," "lipid source," and "carbohydrate source," especially when read in view of the specification. Applicants submit that the phrases "protein source," "lipid source," and "carbohydrate source" are phrases used

frequently by the skilled artisan. Indeed, a seemingly endless number of articles, publications, patents, etc. use the phrases "protein source," "lipid source," and "carbohydrate source," and it is understood that the skilled artisan would know what is meant by these phrases. Further, the specification even expressly discloses specific sources of proteins, lipids, and carbohydrates. See, specification, page 7, lines 5-25. As such, even if the skilled artisan did not know what is meant by the phrases "protein source," "lipid source," and "carbohydrate source," which Applicants submit is not the case, the specification provides more than enough guidance to determine what substances would qualify as such.

Moreover, the Patent Office asserts that "[o]ne of skill in the art would understand that via metabolic pathways raw materials such as glucose are used to make amino acids and proteins or used to make lipids, therefore it is unclear if said carbohydrate is a 'protein source', a 'lipid source' or a 'carbohydrate source'." See, Office Action, page 4, line 20-page 5, line 2. Applicants disagree and submit that this is not a correct statement. For example, glucose is, for example, free of nitrogen and can never be converted to amino acids or proteins. In contrast, and as discussed above, the skilled artisan will immediately appreciate that "a protein source" is any material that proteins may be derived from, "a lipid source" is any material that lipids may be derived from, and "a carbohydrate source" is any material that carbohydrates may be derived from.

For at least the above-mentioned reasons, Applicants respectfully submit that Claims 1 and 3-12 satisfy the definiteness requirements under 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of Claims 1 and 3-12 under 35 U.S.C. §112, second paragraph, be reconsidered and withdrawn.

In the Office Action, Claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Diab. Nutr. Metab. 1992, 5, p295-297 to Genovese et al. ("*Genovese*") in view of J. Clin. Invest. 1985, 75, pages 608-613 to Florent et al. ("*Florent*"). For at least the reasons set forth below, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Independent Claim 13 recites, in part, methods for treating and/or improving insulin resistance by administering to a patient in need of same an effective amount of a composition comprising lactulose, wherein the composition is administered between 3 and 7 hours before a

meal. Surprisingly, the present inventors have found that acetogenic fibers have significant effects in improving insulin sensitivity, and in particular, in reestablishing normal insulin sensitivity and thus a normal systemic metabolism. See, specification, page 4, lines 15-17. Without wishing to be bound to any theory it is presently assumed that an increased amount of acetate in blood and tissues – resulting from an administration of a composition according to the present invention results in reduced lipolysis, *i.e.*, a reduced liberation of glycerol and fatty acids from tissues into the blood. This could result in a reduction in the amount of free fatty acids inactivating insulin receptors, which, in turn, could result in an improvement in insulin sensitivity even to the levels present in healthy persons. See, specification, page 5, lines 17-22. In contrast, Applicants submit that the cited references are deficient with respect to the present claims.

For example, *Genovese* and *Florent* fail to disclose or suggest methods for treating and/or improving insulin resistance comprising administering lactulose to a patient, wherein the composition is administered between 3 and 7 hours before a meal as required, in part, by independent Claim 13. Instead, *Genovese* is entirely directed to a preliminary study to evaluate whether a purified form of lactulose has any effect on glucose tolerance in non-insulin dependent diabetic patients (NIDD). See, *Genovese*, Introduction, paragraph 4. However, at no place in the disclosure does *Genovese* disclose or suggest any time frame when the lactulose is to be administered and fails to even teach that insulin resistance can be improved. Instead, *Genovese* only teaches that blood glucose levels could be reduced.

Florent is entirely directed to studies to investigate the effects of a repeated load of an unabsorbable carbohydrate on the intracolonic metabolism (including H2 production) of this sugar. See, *Florent*, page 608, column 2, first full paragraph. Indeed, *Florent* merely shows that a chronic load of non-absorbable sugar changes colonic bacterial metabolic pathways resulting in an improved ability of the bacteria to digest carbohydrates. *Florent*, however, does not teach or suggest that giving lactulose can reduce insulin resistance or that lactulose should be administered 3-7 hours before a meal. In contrast to the Patent Office's assertion, the disclosure of a time of lactulose peak concentration has nothing to do with administering lactulose with respect to meal timing. Therefore, the combination of *Genovese* and *Florent* fails to disclose or suggest each and every element of the present claims.

For at least these reasons, Applicants respectfully submit that the obviousness rejection of Claim 13 is improper and that the cited references fail to disclose or suggest each and every element of the presently claimed subject matter.

Accordingly, Applicants respectfully request that the obviousness rejection of Claim 13 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

K&L GATES ~~LLP~~

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4204

Dated: October 26, 2010